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Spring/Summer 2003

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The Reporter is published by the Massachusetts Department of Public Health, Division of Food and Drugs, Food Protection Program and the Division of Community Sanitation. For further information on these and other topics, Food Protection Program staff may be reached by calling 617-983-6712 and Division of Community Sanitation staff may be reached by calling 617-983-6762.

This publication is sent to all Boards of Health in the Commonwealth. It is requested that a copy be circulated to all board members and interested employees. Other interested individuals and agencies may request a copy by contacting the Editor.

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Letter from the Directors:

Paul J. Tierney, Division of Food and Drugs, Food Protection Program
Howard S. Wensley, M.S., C.H.O., Division of Community Sanitation



Despite the challenges of the present budget constraints and staff shortages, the Division of Food and Drugs' Food Protection Program and the Division of Community Sanitation continue to strive to fulfill their mission of inspecting facilities, responding to consumer issues, and updating regulatory requirements. The budgetary constraints have been difficult, however all mandated requirements are being fulfilled, and staff continue to work with zeal and responsibility.

During Winter 2002, the Food Protection Program developed a vulnerability assessment evaluation tool, the Food Security Survey for food manufacturers and distributors. More than 150 evaluations have been completed. After completing each survey (The front page of the survey is on page 6.), the inspector provides educational material to the person in charge, including the Food Security Planning brochure for wholesale dairies, seafood dealers, fppd processors, and distributors, (Page 7.), which was developed by the Food Protection Program (FPP) from FDA (U.S. Food and Drug Administration), USDA (U.S. Department of Agriculture), and the WHO (United Nations World Health Organization) guidance documents. In addition, a brochure was developed by the FPP for retail food establishments (page 13.)

In conjunction with the food security work being undertaken by the Food Protection Program, this edition of THE REPORTER includes two recently released FDA food security guidance documents, one for food producers and processors (Page 17.) and the other for retail food stores and food service establishments. (Page 27.)

In October 2002, 105 CMR 570.000: *The Manufacture, Collection, and Bottling of Waters and Carbonated Nonalcoholic Beverages* was promulgated. In November 2002, a public hearing was held on the proposed revisions of 105 CMR 561.000: *Frozen Desserts and Frozen Dessert Mixes*. Final promulgation by the Massachusetts Secretary of State is expected during Summer 2003.

Two initiatives, begun in Fall 2001 have produced noteworthy educational training and curriculum materials.

- The FPP developed a two-day workshop for local health agents on the investigation of foodborne illnesses with funding from the CDC (U.S. Centers

for Disease Control and Prevention) Epidemiology Laboratory Capacity grant. FPP staff conducted the training at five workshops across the state that were co-sponsored by the Massachusetts Health Officers Association, and attended by approximately 125 local health agents. In addition to the training provided, the FPP met with nine of the largest Boards of Health to identify ways in which the Department can help local communities improve the surveillance, reporting and investigation of foodborne illness outbreaks.

- The FPP also developed a two-day workshop for local health agents entitled “Validation and Verification of HACCP Plans in Retail Food Establishments.” This course was developed with funds from an FDA Innovative Grant awarded to the state to develop training for retail food regulators responsible for evaluating mandatory HACCP plans. FPP staff conducted training for approximately 85 local health agents in three workshops co-sponsored by the MHOA. Instructional materials that have been developed to train retail food regulators are now available upon request.

Recently, the FPP applied to the FDA for a Small Conference Grant to conduct a forum for a broad-based discussion of food safety and security. Notification is expected soon.

In May 2003, Massachusetts hosted the Northeast Food and Drugs Official Association Spring meeting. More than 100 food and drugs officials from government and industry from throughout the Northeastern United States and Eastern Canada gathered in Plymouth for the three-day meeting. For 2 days prior to this gathering, the Northeast Regional Food Security Committee conducted a forum to discuss and plan issues related to regional food security initiatives.

The Division of Community Sanitation will shortly begin a major effort to review and update Chapter II of the State Sanitary Code, Minimum Standards of Fitness for Human Habitation. The Division has assembled an advisory committee consisting of representatives from the rental housing industry, legal services, the City of Boston, MHOA, MEHA, MABH, the City of Springfield and the Western Massachusetts Public Health Association.

This project that is intended to take 18-24 months will review the entire set of regulations. The goal of this committee is to make recommendation for change in order to eliminate identified areas of confusion or lack of clarity, to amend/delete existing regulations that may no longer be relevant, to allow wherever possible new technology, to better coordinate with other specialized codes such as building, plumbing a wiring, and to look at the inclusion of certain indoor air quality standards.

If you have any particular concerns or suggestions, please let us know either in writing, Division of Community Sanitation, 305 South Street, Jamaica Plain, MA 02130 or by e-mail-howard.wensley@state.ma.us.

During Winter 2003, Scott Allen was promoted to Supervisor of the Food Processing Unit and Sean Bowen was promoted to Supervisor of the Seafood Unit. Luisa Siniscalchi, Senior Inspector in the Retail Food Unit, left the FPP. Roy Sanderson joined the FPP staff to coordinate the Program’s Food Security activities. ✂

Food Security

Roy D. Sanderson, MPH, JD

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides the states with specific guidance on protecting the security and safety of the food supply. Acting on this guidance, the Massachusetts department of Public Health Food Protection Program has conducted threat assessments of various food processing and manufacturing firms located throughout the state. Food security surveys conducted by State Food Inspectors provide information on the level of food security awareness among industry and help individual food processors make improvements in their food security programs. To date over 150 food processing facilities have been surveyed. The surveys provide important information on product recall capabilities, and also highlight food vulnerability areas during transportation and processing.

Food Security Survey information is used in several ways. Inspectors use it to identify problem areas during plant inspections. Plant managers use it to identify areas where improvements can be made. Educators use it to develop food security training material. Various food security planning documents and resource guides are available from the Department of Public Health's Food Protection Program. These documents are available in hard copy or they may be downloaded from our website at www.state.ma.us/dph/fpp.

Effective food security programs integrate an operational risk management approach that encourages cooperation between government and industry. Implementing a risk management approach requires food facility managers to: (1) identify the hazards, (2) assess the risk, (3) analyze risk control measures, (4) make control decisions, (5) implement risk controls, and (6) supervise and review efforts made. A risk management approach is not a "wait and see" approach. Our food security programs must include ongoing threat evaluations as well as cooperative efforts between government and industry aimed at reducing the vulnerability of the food supply to terrorist threats. Risk management principles must be applied to personnel, products and property in order to determine an appropriate response for a particular food processing facility.

Thinking about food security is not as simple as thinking about who stole the lunch from the office refrigerator. The missing lunch suggests that we need to take steps to limit access to the office food supply. Maybe on a larger scale we need to take steps to limit access to America's food supply. Of course access is not the only issue. We must explore the vulnerability connections that link the farm to the food processor and to the retail food facility. If we know the risk and take steps to reduce it, we can appreciate the missing lunch and all the things that could have been done to it on along the way to the table.✂

COMMONWEALTH OF MASSACHUSETTS
Department of Public Health Division of Food and Drugs
Food Protection Program
305 South Street, Jamaica Plain, MA 02130

FOOD SECURITY SURVEY

1. OFFICIAL LICENSE Facility Name and Address

Name: _____

Street: _____

Town/Zip: _____

Email Address: _____

2 Date of Survey: _____

3 Inspector: _____

4 License/Permit Number: _____

5 Telephone #: _____

6 FAX #: _____

7 Emergency Tele. #: _____

6. Type of Food Product: (check ALL that apply)

☐ **Dairy** ☐ **Seafood** ☐ **Food(general)** ☐ **Bottled water/Beverages** ☐ **Meat & Poultry**

7a. Type of Activity:

☐ **Manufacturer** ☐ **Warehouse** ☐ **Re-packer**

7b. Gross Annual Food Sales:

\$ _____

8. Plant Size : ☐ **<10,000 sq ft** ☐ **10 - 25,000 sq ft** ☐ **25 - 50,000 sq ft** ☐ **50 - 100,000 sq ft** ☐ **>100,000 sq ft**

9. Usual Time of Operation: Circle Days of the Week: **S** **M** **T** **W** **T** **F** **S** Hours: _____ **AM/PM** _____ **AM/PM**

10. Water Supply: ☐ **Public** ☐ **Well** ☐ **Other** _____

11. Number of Employees: ☐ **fewer than 10** ☐ **10-50** ☐ **51-100** ☐ **101-200** ☐ **more than 200**

FINISHED PRODUCT

The firm maintains an inventory of finished products.

The firm has a written recall procedure in place.

There is a person appointed or team responsible for trace-back and product verification.

For trace-back, tracking and product verification, lot numbers or additional measures are used.

In the last three years, trace back or recall exercises have been conducted at the plant.

On-site and off-site warehouses that store raw and finished food product are secure.

Finished product is shipped in:

- a. Company-owned vehicles
 - b. Common carrier
 - c. Rental or leased vehicles
- Loaded vehicles are sealed before departure.
- The integrity of the seal is verified at the final destination.
- If a loaded vehicle has multiple delivery stops, the vehicle is re-sealed after each delivery.

SELF-INSPECTION

The possibility of deliberate biological attacks on the food supply is becoming our new reality. In these times of terrorist threats, it is evident that our nation's food supply is a vulnerable area that we must look at more closely. The security of your facility is in your hands, and self-inspection is the first step in your Food Security Plan, as well as a cost effective way to maintain your firm's interests.

So take a walk through your facility using the attached checklist. This is a basic guide. Nobody knows your business better than you, so you can add to the checklist those items that are specific to your establishment.

Become familiar with "Public Health Security and Bioterrorism Preparedness and Response Act of 2002", Title III, Subtitle A, Protection of the Food Supply at:

www.cfsan.fda.gov/~dms/ftterr.html

Other website sources:

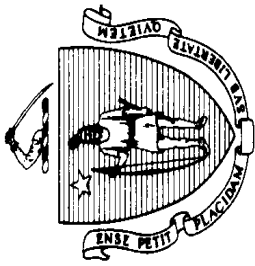
www.state.ma.us/dph/fpp

www.state.ma.us/dph/bioterrorism/advisorygrps/index.htm

www.cfsan.fda.gov/~dms/secguid.html

www.usda.gov/homelandsecurity/homeland.html

www.bt.cdc.gov



MASSACHUSETTS

DIVISION OF FOOD AND DRUGS
FOOD PROTECTION PROGRAM

FOOD SECURITY PLANNING

A SELF-INSPECTION CHECKLIST for Dairies, Seafood Dealers, Food Processors and Distributors

FOOD SECURITY MANAGEMENT

The facility has been evaluated for food security.

The firm has a food security plan.

A food security plan has been implemented at the facility.

The firm conducts food security inspections of the facility.

Appropriate management personnel have received training in food security.

The firm has established a food security management team and/or has a food security professional.

In case of a food security emergency, responsible personnel know whom to contact: a. Internal

b. External (Law Enforcement)

PLANT PERSONNEL

Pre-hiring background checks of prospective employees are conducted.

Only authorized personnel are allowed access to all parts of the facility.

The plant has a system of positive identification and recognition for all personnel, e.g., issuing photo identification badges with individual control numbers.

Personnel have been trained in plant security procedures, and have

been instructed to watch for and report any unusual activities within the plant or on plant grounds.

There are restrictions on personal items brought into the plant.

The firm maintains an up-to-date roster of plant personnel.

INSIDE SECURITY

Based on risk, areas within the facility have been designated as restricted areas (utilities, e.g. ventilation, water, refrigeration)

Restricted areas are clearly marked and secured.

Hazardous chemical storage areas are secured.

Unauthorized employees, visitors, etc. are prevented from accessing restricted areas, unless accompanied by authorized plant personnel.

The facility is equipped with an emergency alert system.

The facility's computer data systems are adequately protected from unauthorized access.

EXTERNAL SECURITY

The outside perimeter is secured with:

a. fences, b. entry check points, c. card entry, d. other

The outside perimeter is:

a. lighted; b. monitored by cameras,

c. patrolled, d. other
Access points into all facilities are secured at all times.

All truck deliveries are verified against a roster of scheduled deliveries.

RAW MATERIALS

The facility uses only approved sources for all ingredients, packaging and labels.

Access to outside wells, potable water and ice-making equipment are secured.

Loading docks are secured when not in use.

The firm requests locked and sealed delivery vehicles/containers.

Before off-loading or receipt, the firm matches all incoming paperwork with shipments.

The firm inspects incoming ingredients, packaging, labels, and product returns for signs of tampering (e.g. abnormal powders, liquids, or odors) or counterfeiting (inappropriate product identity, labeling, product lot coding or specifications).

The firm has quarantine and release procedures in place.

The firm performs security inspections of all storage facilities, including temporary storage vehicles regularly. The firm keeps these inspections on file.

11/1/02

MDPH Food Protection Program Food Emergency Preparedness and Response Planning

Massachusetts Department of Public Health
National Food Recalls, News Alerts And Warnings
General Food Safety And Security Preparedness Information
Protecting the Food Supply in a Power Outage
Interruption of Potable Water Supply
Flooding and Sewage Back-ups in Food Operations
Evaluating Foods for Salvage and Reconditioning
Monitoring Emergency Food Supplies and Operations

Massachusetts Department of Public Health

MDPH Food Protection Program

<http://www.state.ma.us/dph/fpp/fpp.htm>

MDPH Food safety and security information for MA wholesale and retail food industries, local food regulatory agencies, food safety educators and consumers.

MDPH Foodborne Illness Investigation Manual

<http://www.state.ma.us/dph/fpp/refman.htm>

This reference is part of MDPH's focus on providing more trainings and technical assistance for local boards of health and health department staff. The purpose of the manual is to guide local boards of health and health department staff through foodborne illness investigation and control. It is designed as a comprehensive reference covering both epidemiologic and environmental aspects of a foodborne illness investigation.

MDPH Emergency Preparedness

www.state.ma.us/dph/bioterrorism/advisorygrps/

and Response Advisory Committees Website

[index.html](http://www.state.ma.us/dph/bioterrorism/advisorygrps/index.html)

This site will be evolving as new information is added regarding the committees and various work-groups that are working on bioterrorist related activities, such as the Food Vulnerability Work Group, MEMA, Mass Hospital Preparedness and CDC, Funding,

MDPH Emergency Preparedness

[http://www.state.ma.us/dph/topics/bioterrorism/bt.](http://www.state.ma.us/dph/topics/bioterrorism/bt.htm)

and Response

[htm](http://www.state.ma.us/dph/topics/bioterrorism/bt.htm)

General policies, procedures, fact sheets, links and updates on MDPH emergency preparedness and response activities.

National Food Recalls, News Alerts And Warnings

FDA Product Recalls, Alerts and Warnings (Archives)

<http://www.fda.gov/oc/po/firmrecalls/archive.html>

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

FSIS/USDA Recall Information Center

http://www.fsis.usda.gov/OA/recalls/rec_intr.htm
Introduction, FSIS Recall Information Center

During a meat or poultry recall, FSIS protects the public health by ensuring that potentially hazardous foods are removed from commerce as quickly as possible. The primary role of FSIS is to closely monitor the effectiveness of the firm's recall procedures and to provide scientific and technical advice.

General Food Safety And Security Preparedness Information**USDA Keeping America's Food and Agriculture Safe**

<http://www.usda.gov/homelandsecurity/help.html>

"What Can You Do?" English and Spanish posters and fact sheets for meal providers, processors and producers.

**USDA and FSIS Homeland Security/
Biosecurity Resources**

<http://www.fsis.usda.gov/oa/topics/biosecurity.htm>

Food Biosecurity Topics Page

FSIS guideline for food processors and other general information on food security.

**FDA Food Security Preventive Measures
Guidance for Food Producers, Processors,
Transporters, and Retailers**

<http://www.cfsan.fda.gov/~dms/secguid.html>

This guidance represents FDA's current thinking on appropriate measures that can be taken by food establishments to minimize the risk of food being subjected to tampering or criminal or terrorist actions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. This guidance is being issued in accordance with FDA's Good Guidance Practices regulation (21 CFR 10.115; 65 FR 56468; September 19, 2000).

**FoodSafety.Gov - Countering Bioterrorism
And Other Threats To The Food Supply**

<http://www.foodsafety.gov/~fsg/bioterr.html>
www.foodsafety.gov - Countering Bioterrorism
and Other Threats to the Food Supply

Useful links to federal, state, local and international government web sites relative to food security.

FDA's Food Safety and Terrorism Home Page

<http://www.cfsan.fda.gov/~dms/fsterr.html>

US FDA Public Health and Bioterrorism Preparedness and Response Act of 2002, Title III, Subtitle A, Protection of the Food Supply

**CDC Public Health Emergency Preparedness
and Response**

www.bt.cdc.gov

This site contains agent and threat fact sheets, current press releases and media briefings, detailed information for health professionals, training opportunities and preparation and planning documents.

Protecting the Food Supply in a Power Outage

Keeping Foods Safe During an Emergency

<http://www.fsis.usda.gov/oa/pubs/pofeature.htm>
Keeping Food Safe During An Emergency

A fact sheet in English and Spanish that will help consumers make the right decisions for keeping their food supply safe during an emergency.

Guidelines for Food Safety During Temporary Power Outages

<http://foodsafety.ucdavis.edu/PowerOutageGuidanceFinal.pdf>

Guideline issued by the CA Department of Health Services' Food and Drug Branch on behalf of the California Food Safety Task Force to provide guidance to the retail food industry. It was developed through the collaborative efforts of the Retail Food Industry, food safety experts at the University of California at Davis, the California Conference of Directors of Environmental Health, California Conference of Local Health Officers, and the California Department of Health Services.

Interruption of Potable Water Supply

MA DEP Handbook for Water Supply Emergencies

<http://www.state.ma.us/dep/brp/dws/files/emerhdbk.doc>

The purpose of this document is to serve as a guide to the water suppliers during preparation of their *Emergency Response Plan*, as well as, to be followed during emergencies. Identifies the steps that a public water supplier must take during an emergency according to its severity using a Level I, II, III, IV, and V status with Level I being routine problems such as main breaks, and Level V being a nuclear disaster or major terrorist act.

What Does a Boil Order Mean?

<http://missourifamilies.org/features/nutritionarticles/nut68.htm>
What Does a Boil Order Mean?

Consumer information when affected by a boil water order. University of Missouri Outreach and Extension

Flooding and Sewage Back-ups in Food Operations

What can I safely do with the food that went through a flood?

http://msucare.com/health/food_safety/foodfaq46.html

A Mississippi State University Extension Services publication with recommendations for discarding and sanitizing food supplies affected by a flood.

MDPH Storm Fact Sheet

<http://www.state.ma.us/dph/dcs/stormfct.htm>

General flooding information that also includes some consumer guidelines for food safety during power failures.

Evaluating Food for Salvage and Reconditioning

MDPH Guidelines for Evaluating Food products for Salvage and Reconditioning <http://www.state.ma.us/dph/fpp/web-fp-01.pdf>

These guidelines should be used while conducting an inspection to evaluate food that has potentially been exposed to contamination for salvage and reconditioning. The guidelines address the basic information an inspector needs for inspecting potentially contaminated food, and the procedures to follow when a variety of violations and conditions are encountered. As with any type of inspection or investigation, proper written documentation is required.

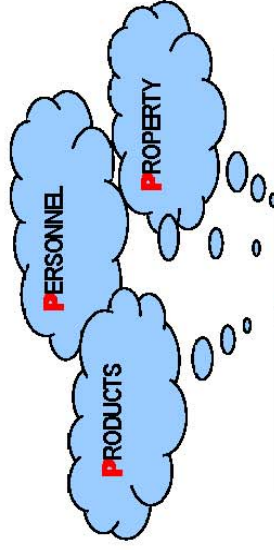
Monitoring Emergency Food Supplies and Operations

Food Safety Principles for Food Workers <http://www.state.ma.us/dph/fpp/retail/training.htm>
Massachusetts Retail Food Safety Information -
Training Resources

A simple two page food-safety brochure with basic food safety principles and practices available in English, Haitian, Portuguese, Spanish and Vietnamese. These brochures, developed by the MA Partnership for Food Safety Education, can be distributed to persons-in-charge of emergency food operations and their workers, if necessary.

Cooking for Groups: A Volunteer's Guide to Food Safety <http://www.fsis.usda.gov/oa/pubs/cfg/cfg.htm>
HOME PAGE - Cooking for Groups: A Volunteer's
Guide to Food Safety

The information provided in this FSIS publication was developed as a guide for consumers who are preparing food for large groups. ✂



SELF-INSPECTION PROGRAM

A self-inspection program can help you reduce the vulnerability of your food facility to terrorist threats and to criminal acts of product tampering. Food has been used as a vehicle to spread chemical and biological agents. Product tampering is a concern for all food facility operators. It may cause harm to customers, and it may result in serious economic consequences for the food service facility.

A self-inspection program is an important preventive measure that will improve food security at your facility and may reduce your liability. This self-inspection checklist is a guide to help you evaluate the food security program at your facility. A food security program will help protect your customers, your employees, and your business.

Please modify this checklist to meet the unique circumstances of your restaurant or retail food facility.

*Massachusetts Department of Public Health
Division of Food and Drugs
Food Protection Program
May 2003*

FOOD SECURITY MANAGEMENT

- ☐ The food facility has been evaluated for food security.
- ☐ The food facility has a food security plan.
- ☐ There is an assigned food security coordinator.
- ☐ Personnel have received food security training.
- ☐ Food security inspections are regularly performed by supervisors.
- ☐ Personnel know what to do if they encounter a product tampering incident.
- ☐ In case of an emergency, personnel know who to contact:

Internal: Supervisor

External: Police

Fire

Board of Health



Massachusetts
Division of Food and Drugs
Food Protection Program

Food Security Planning

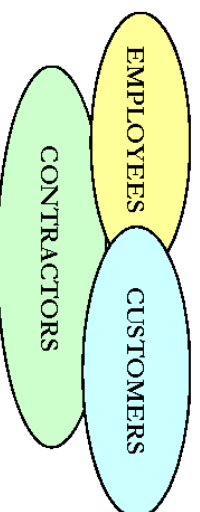
**Self-Inspection Checklist
for
Restaurants
and
Retail Food Stores**

PERSONNEL



- ☐ Background checks as allowed by law, are done on prospective employees.
- ☐ Employment applications are required.
- ☐ Employment references are checked.
- ☐ Personnel receive food security training when they are hired.
- ☐ Food preparation areas are restricted to authorized personnel.
- ☐ Employees are not allowed to bring personal items into food preparation areas.
- ☐ Employee sick leave policy encourages individuals to report illnesses and not work when they have gastrointestinal symptoms or a communicable disease.
- ☐ Customers are restricted to public areas.
- ☐ Contractors are restricted to their work required areas.
- ☐ Contractors and vendors are monitored while they are at the food facility.

PERSONNEL CONNECTIONS



PROPERTY



- ☐ A closed circuit television system is used to monitor high risk areas inside the facility.
- ☐ Security cameras are used to monitor the loading dock and exits.
- ☐ Doors opening onto the loading dock are kept locked when not in use.
- ☐ All truck shipments (incoming and outgoing) are monitored by food service employees.
- ☐ Products are inspected upon delivery.
- ☐ There is good lighting for all high risk areas at the facility.
- ☐ Hazardous chemicals including any pesticides are kept locked in a secure area.
- ☐ High risk areas are marked "employees only" and access is limited to employees who work in the area.
- ☐ There is a key control system for store keys.

You hold the key to a safe and secure food operation!

Food Security Websites

www.state.ma.us/dph/fpp
www.state.ma.us/dph/fpp/retail/training.htm
www.cfsan.fda.gov/~dms/fserr.html
www.bt.cdc.gov

PRODUCTS



- ☐ Products are purchased from reputable established sources.
- ☐ Purchase records are maintained for product trace back and recalls.
- ☐ Products arrive at the food facility in clean and secure transport vehicles.
- ☐ Products are never left unsupervised on the loading dock.
- ☐ Products are inspected for tampering prior to preparation or service.
- ☐ The facility has guidelines for handling product tampering incident.
- ☐ Food items are prepared by personnel trained in food safety and food security procedures.
- ☐ Potable water is used for rinsing and for preparing food items
- ☐ Salad bars, and self-serve carts are closely monitored by staff to prevent contamination and product tampering.

MONITOR HIGH RISK OPERATIONS!



INFORMATION

If you have questions about food security,
 Contact:
 Massachusetts Department of Public Health
 Division of Food and Drugs
 617-983-6700.

US FDA Issues New Food Security Preventive Measures Guidance

The U.S. Food and Drug Administration announced the availability of guidance documents designed to help food manufacturers minimize the risk of tampering or other malicious, criminal or terrorist actions.

Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance (Final)
<http://www.cfsan.fda.gov/~dms/secguid6.html>

The final guidance will help operators of food establishments(e.g., firms that produce, process, store, repack, re-label, distribute, or transport food or food ingredients) identify preventive measures to improve the security of their operations.

Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (Proposed)

<http://www.cfsan.fda.gov/~dms/secguid5.html>

This proposed guidance covers food stores and food service establishments. It also identifies preventive measures that operators can take to minimize the security risks to their products.

FDA's guidance documents are NOT regulations and are NOT mandatory. They set forth voluntary recommendations from FDA. FDA has found that developing guidance is the fastest way to circulate these recommendations to the industry, while allowing flexibility to alter recommendations as science and intelligence information changes.

A fact sheet is on the web at:

<http://www.fda.gov/oc/factsheets/foodsecurity.html> ☒

U. S. Department of Health and Human Services
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 21, 2003

Guidance for Industry

Food Producers, Processors, and Transporters:

Food Security Preventive Measures Guidance

This guidance represents the Agency's current thinking on the kinds of measures that food establishments may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Purpose and Scope:

This guidance is designed as an aid to operators of food establishments (firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients). This is a very diverse set of establishments, which includes both very large and very small entities.

This guidance identifies the kinds of preventive measures operators of food establishments may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It is relevant to all sectors of the food system, including farms, aquaculture facilities, fishing vessels, producers, transportation operations, processing facilities, packing facilities, and warehouses. It is not intended as guidance for retail food stores or food service establishments.

Operators of food establishments are encouraged to review their current procedures and controls in light of the potential for tampering or other malicious, criminal, or terrorist actions and make appropriate improvements. FDA recommends that the review include consideration of the role that unit and distribution packaging might have in a food security program. This guidance is designed to focus operator's attention sequentially on each segment of the farm-to-table system that is within their control, to minimize the risk of tampering or other malicious, criminal, or terrorist action at each segment. To be successful, implementing enhanced preventive measures requires the commitment of management and staff. Accordingly, FDA recommends that both management and staff participate in the development and review of such measures.

Limitations:

Not all of the guidance contained in this document may be appropriate or practical for every food establishment, particularly smaller facilities and distributors. FDA recommends that operators review the guidance in each section that relates to a component of their operation, and assess which preventive measures are suitable. Example approaches are provided for many of the preventive measures listed in this document. These examples should not be regarded as minimum standards. Nor should the examples provided be considered an inclusive list of all potential approaches to

achieving the goal of the preventive measure. FDA recommends that operators consider the goal of the preventive measure, assess whether the goal is relevant to their operation, and, if it is, design an approach that is both efficient and effective to accomplish the goal under their conditions of operation.

Structure:

This guidance is divided into five sections that relate to individual components of a food establishment operation: management; human element - staff; human element - public; facility; and operations.

Related Guidance:

FDA has published a companion guidance document on food security entitled, "Importers and filers: Food security preventive measures guidance" to cover the farm-to-table spectrum of food production. This document is available at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

Additional Resources:*

A process called Operational Risk Management (ORM) may help prioritize the preventive measures that are most likely to have the greatest impact on reducing the risk of tampering or other malicious, criminal, or terrorist actions against food. Information on ORM is available in the Federal Aviation Administration (FAA) System Safety Handbook, U.S. Department of Transportation, FAA, December 30, 2000, Chapter 15, Operational Risk Management. The handbook is available at: http://www.asy.faa.gov/Risk/SSHandbook/Chap15_1200.PDF.

The U.S. Department of Transportation, Research and Special Programs Administration has published an advisory notice of voluntary measures to enhance the security of hazardous materials shipments. It is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-3636-filed.pdf. The notice provides guidance to shippers and carriers on personnel, facility and en route security issues.

The U.S. Postal Service has prepared guidance for identifying and handling suspicious mail. It is available at: <http://www.usps.com/news/2001/press/mailsecurity/postcard.htm>.

The Federal Anti-Tampering Act (18 USC 1365) makes it a federal crime to tamper with or taint a consumer product, or to attempt, threaten or conspire to tamper with or taint a consumer product, or make a false statement about having tampered with or tainted a consumer product. Conviction can lead to penalties of up to \$100,000 in fines and up to life imprisonment. The Act is available at: <http://www.fda.gov/opacom/laws/fedatact.htm>.

The National Infrastructure Protection Center (NIPC) serves as the federal government's focal point for threat assessment, warning, investigation, and response for threats or attacks against U.S. critical infrastructure. The NIPC has identified the food system as one of the eight critical infrastructures, and has established a public-private partnership with the food industry, called the Food Industry Information and Analysis Center (Food Industry ISAC). The NIPC provides the Food Industry ISAC with access, information and analysis, enabling the food industry to report, identify, and reduce its vulnerabilities to malicious attacks, and to recover from such attacks as quickly as possible. In particular, the NIPC identifies credible threats and crafts specific warning messages to the food industry. Further information is available at <http://www.nipc.gov/> and <http://www.foodisac.org/>.

Finally, some trade associations have developed food security guidance that is appropriately focused

for that specific industry. For example, the International Dairy Food Association has developed a food security guidance document as an aid to the dairy industry.

FDA encourages other trade associations to evaluate the preventive measures contained in this FDA guidance document and adapt them to their specific products and operations and to supplement this guidance with additional preventive measures when appropriate. FDA welcomes dialogue on the content of sector specific guidance with appropriate trade associations.

Food Establishment Operations:

Management

FDA recommends that food establishment operators consider:

- Preparing for the possibility of tampering or other malicious, criminal, or terrorist actions
 - assigning responsibility for security to knowledgeable individual(s)
 - conducting an initial assessment of food security procedures and operations, which we recommend be kept confidential
 - having a security management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected product
 - planning for emergency evacuation, including preventing security breaches during evacuation
 - maintaining any floor or flow plan in a secure, off-site location
 - becoming familiar with the emergency response system in the community
 - making management aware of 24-hour contact information for local, state, and federal police/fire/rescue/health/homeland security agencies
 - making staff aware of who in management they should alert about potential security problems (24-hour contacts)
 - promoting food security awareness to encourage all staff to be alert to any signs of tampering or other malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and reporting any findings to identified management (for example, providing training, instituting a system of rewards, building security into job performance standards)
 - having an internal communication system to inform and update staff about relevant security issues
 - having a strategy for communicating with the public (for example, identifying a media spokesperson, preparing generic press statements and background information, and coordinating press statements with appropriate authorities)
- Supervision
 - providing an appropriate level of supervision to all staff, including cleaning and maintenance staff, contract workers, data entry and computer support staff, and especially, new staff
 - conducting routine security checks of the premises, including automated

manufacturing lines, utilities and critical computer data systems (at a frequency appropriate to the operation) for signs of tampering or malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions

☐ Recall strategy

- identifying the person responsible, and a backup person
- providing for proper handling and disposition of recalled product
- identifying customer contacts, addresses and phone numbers

☐ Investigation of suspicious activity

- investigating threats or information about signs of tampering or other malicious, criminal, or terrorist actions
- alerting appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions

☐ Evaluation program

- evaluating the lessons learned from past tampering or other malicious, criminal, or terrorist actions and threats
- reviewing and verifying, at least annually, the effectiveness of the security management program (for example, using knowledgeable in-house or third party staff to conduct tampering or other malicious, criminal, or terrorist action exercises and mock recalls and to challenge computer security systems), revising the program accordingly, and keeping this information confidential
- performing random food security inspections of all appropriate areas of the facility (including receiving and warehousing, where applicable) using knowledgeable in-house or third party staff, and keeping this information confidential
- verifying that security contractors are doing an appropriate job, when applicable

Human element - staff

Under Federal law, food establishment operators are required to verify the employment eligibility of all new hires, in accordance with the requirements of the Immigration and Nationality Act, by completing the INS Employment Eligibility Verification Form (INS Form I-9). Completion of Form I-9 for new hires is required by 8 USC 1324a and nondiscrimination provisions governing the verification process are set forth at 8 USC 1324b.

FDA recommends that food establishment operators consider:

☐ Screening (pre-hiring, at hiring, post-hiring)

- examining the background of all staff (including seasonal, temporary, contract, and volunteer staff, whether hired directly or through a recruitment firm) as appropriate to their position, considering candidates' access to sensitive areas of the facility and the degree to which they will be supervised and other relevant factors (for example, obtaining and verifying work references, addresses, and phone numbers, participating in one of the pilot programs managed by the Immigration and Naturalization Service and the Social Security Administration [These programs provide electronic confirmation of employment eligibility for newly hired employees. For more information call the INS SAVE Program toll free at 1-888-464-4218, fax a request for information to (202) 514-9981, or write to US/INS, SAVE Program, 425 I Street,

NW, ULLICO-4th Floor, Washington, DC 20536. These pilot programs may not be available in all states], having a criminal background check performed by local law enforcement or by a contract service provider [Remember to first consult any state or local laws that may apply to the performance of such checks])

- ☐ Note: screening procedures should be applied equally to all staff, regardless of race, national origin, religion, and citizenship or immigration status.
- ☐ Daily work assignments
 - knowing who is and who should be on premises, and where they should be located, for each shift
 - keeping information updated
- ☐ Identification
 - establishing a system of positive identification and recognition that is appropriate to the nature of the workforce (for example, issuing uniforms, name tags, or photo identification badges with individual control numbers, color coded by area of authorized access), when appropriate
 - collecting the uniforms, name tag, or identification badge when a staff member is no longer associated with the establishment
- ☐ Restricted access
 - identifying staff that require unlimited access to all areas of the facility
 - reassessing levels of access for all staff periodically
 - limiting access so staff enter only those areas necessary for their job functions and only during appropriate work hours (for example, using key cards or keyed or cipher locks for entry to sensitive areas, color coded uniforms [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes])
 - ☐ changing combinations, rekeying locks and/or collecting the retired key card when a staff member who is in possession of these is no longer associated with the establishment, and additionally as needed to maintain security
- ☐ Personal items
 - restricting the type of personal items allowed in establishment
 - allowing in the establishment only those personal use medicines that are necessary for the health of staff and ensuring that these personal use medicines are properly labeled and stored away from food handling or storage areas
 - preventing staff from bringing personal items (for example, lunch containers, purses) into food handling or storage areas
 - ☐ providing for regular inspection of contents of staff lockers (for example, providing metal mesh lockers, company issued locks), bags, packages, and vehicles when on company property (Remember to first consult any federal, state, or local laws that may relate to such inspections)
- ☐ Training in food security procedures
 - incorporating food security awareness, including information on how to prevent, detect, and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including seasonal, temporary, contract, and volunteer staff

- providing periodic reminders of the importance of security procedures (for example, scheduling meetings, providing brochures or payroll stuffers)
- encouraging staff support (for example, involving staff in food security planning and the food security awareness program, demonstrating the importance of security procedures to the staff)
- Unusual behavior
 - watching for unusual or suspicious behavior by staff (for example, staff who, without an identifiable purpose, stay unusually late after the end of their shift, arrive unusually early, access files/information/areas of the facility outside of the areas of their responsibility; remove documents from the facility; ask questions on sensitive subjects; bring cameras to work)
- Staff health
 - being alert for atypical staff health conditions that staff may voluntarily report and absences that could be an early indicator of tampering or other malicious, criminal, or terrorist actions (for example, an unusual number of staff who work in the same part of the facility reporting similar symptoms within a short time frame), and reporting such conditions to local health authorities.

Human element -- public

FDA recommends that food establishment operators consider:

- Visitors (for example, contractors, supplier representatives, delivery drivers, customers, couriers, pest control representatives, third-party auditors, regulators, reporters, tours)
 - inspecting incoming and outgoing vehicles, packages and briefcases for suspicious, inappropriate or unusual items or activity, to the extent practical
 - restricting entry to the establishment (for example, checking visitors in and out at security or reception, requiring proof of identity, issuing visitors badges that are collected upon departure, accompanying visitors)
 - ensuring that there is a valid reason for the visit before providing access to the facility - beware of unsolicited visitors
 - verifying the identity of unknown visitors
 - restricting access to food handling and storage areas (for example, accompanying visitors, unless they are otherwise specifically authorized)
 - restricting access to locker room

Facility

FDA recommends that food establishment operators consider:

- Physical security
 - protecting perimeter access with fencing or other deterrent, when appropriate
 - securing doors (including freight loading doors, when not in use and not being monitored, and emergency exits), windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, ice manufacturing and storage rooms, loft areas, trailer bodies, tanker trucks, railcars, and bulk storage tanks for liquids, solids, and compressed gases, to the extent possible (for example, using locks, "jimmy plates," seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes])

- using metal or metal-clad exterior doors to the extent possible when the facility is not in operation, except where visibility from public thoroughfares is an intended deterrent (remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes)
- minimizing the number of entrances to restricted areas (remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes)
- securing bulk unloading equipment (for example, augers, pipes, conveyor belts, and hoses) when not in use and inspecting the equipment before use
- accounting for all keys to establishment (for example, assigning responsibility for issuing, tracking, and retrieving keys)
- monitoring the security of the premises using appropriate methods (for example, using security patrols [uniformed and/or plain-clothed], video surveillance)
- minimizing, to the extent practical, places that can be used to temporarily hide intentional contaminants (for example, minimizing nooks and crannies, false ceilings)
- providing adequate interior and exterior lighting, including emergency lighting, where appropriate, to facilitate detection of suspicious or unusual activities
- implementing a system of controlling vehicles authorized to park on the premises (for example, using placards, decals, key cards, keyed or cipher locks, issuing passes for specific areas and times to visitors' vehicles)
- keeping parking areas separated from entrances to food storage and processing areas and utilities, where practical

□ Laboratory safety

- restricting access to the laboratory (for example, using key cards or keyed or cipher locks [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes])
- restricting laboratory materials to the laboratory, except as needed for sampling or other appropriate activities
- restricting access (for example, using locks, seals, alarms, key cards, keyed or cipher locks) to sensitive materials (for example, reagents and bacterial, drug, and toxin positive controls)
- assigning responsibility for integrity of positive controls to a qualified individual
- knowing what reagents and positive controls should be on the premises and keeping track of them
- investigating missing reagents or positive controls or other irregularities outside a normal range of variability immediately, and alerting appropriate law enforcement and public health authorities about unresolved problems, when appropriate
- disposing of unneeded reagents and positive controls in a manner that minimizes the risk that they can be used as a contaminant

□ Storage and use of poisonous and toxic chemicals (for example, cleaning and sanitizing agents, pesticides)

- limiting poisonous and toxic chemicals in the establishment to those that are required for the operation and maintenance of the facility and those that are being held for sale
- storing poisonous and toxic chemicals as far away from food handling and storage

areas as practical

- limiting access to and securing storage areas for poisonous and toxic chemicals that are not being held for sale (for example, using keyed or cipher locks, key cards, seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any relevant federal, state or local fire codes that may apply before making any changes])
- ensuring that poisonous and toxic chemicals are properly labeled
- using pesticides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (for example, maintaining rodent bait that is in use in covered, tamper-resistant bait stations)
- knowing what poisonous and toxic chemicals should be on the premises and keeping track of them
- investigating missing stock or other irregularities outside a normal range of variation and alerting appropriate law enforcement and public health authorities about unresolved problems, when appropriate

Operations

FDA recommends that food establishment operators consider:

☐ Incoming materials and contract operations:

- using only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators and sources for all incoming materials, including ingredients, compressed gas, packaging, labels, and materials for research and development
- taking reasonable steps to ensure that suppliers, contract operators and transporters practice appropriate food security measures (for example, auditing, where practical, for compliance with food security measures that are contained in purchase and shipping contracts or letters of credit, or using a vendor approval program)
- authenticating labeling and packaging configuration and product coding/expiration dating systems (where applicable) for incoming materials in advance of receipt of shipment, especially for new products
- requesting locked and/or sealed vehicles/containers/railcars, and, if sealed, obtaining the seal number from the supplier and verifying upon receipt, making arrangements to maintain the chain of custody when a seal is broken for inspection by a governmental agency or as a result of multiple deliveries
- requesting that the transporter have the capability to verify the location of the load at any time, when practical
- establishing delivery schedules, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments
- supervising off-loading of incoming materials, including off hour deliveries
- reconciling the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents, taking into account any sampling performed prior to receipt
- investigating shipping documents with suspicious alterations
- inspecting incoming materials, including ingredients, compressed gas, packaging, labels, product returns, and materials for research and development, for signs of tampering, contamination or damage (for example, abnormal powders, liquids,

stains, or odors, evidence of resealing, compromised tamper-evident packaging) or "counterfeiting" (for example, inappropriate or mismatched product identity, labeling, product lot coding or specifications, absence of tamper-evident packaging when the label contains a tamper-evident notice), when appropriate

- evaluating the utility of testing incoming ingredients, compressed gas, packaging, labels, product returns, and materials for research and development for detecting tampering or other malicious, criminal, or terrorist action
- rejecting suspect food
- alerting appropriate law enforcement and public health authorities about evidence of tampering, "counterfeiting" or other malicious, criminal, or terrorist action

□ Storage

- having a system for receiving, storing, and handling distressed, damaged, returned, and rework products that minimizes their potential for being compromised or to compromise the security of other products (for example, destroying products that are unfit for human or animal consumption, products with illegible codes, products of questionable origin, and products returned by consumers to retail stores)
- keeping track of incoming materials and materials in use, including ingredients, compressed gas, packaging, labels, salvage products, rework products, and product returns
- investigating missing or extra stock or other irregularities outside a normal range of variability and reporting unresolved problems to appropriate law enforcement and public health authorities, when appropriate
- storing product labels in a secure location and destroying outdated or discarded product labels
- minimizing reuse of containers, shipping packages, cartons, etc., where practical

□ Security of water and utilities

- limiting, to the extent practical, access to controls for airflow, water, electricity, and refrigeration
- securing non-municipal water wells, hydrants, storage, and handling facilities
- ensuring that water systems and trucks are equipped with backflow prevention
- chlorinating water systems and monitoring chlorination equipment, where practical, and especially for non-municipal water systems
- testing non-municipal sources for potability regularly, as well as randomly, and being alert to changes in the profile of the results
- staying attentive to the potential for media alerts about public water provider problems, when applicable
- identifying alternate sources of potable water for use during emergency situations where normal water systems have been compromised (for example, trucking from an approved source, treating on-site or maintaining on-site storage)

□ Finished products

- ensuring that public storage warehousing and shipping operations (vehicles and vessels) practice appropriate security measures (for example, auditing, where practical, for compliance with food security measures that are contained in contracts or letters of guarantee)

- performing random inspection of storage facilities, vehicles, and vessels
- evaluating the utility of finished product testing for detecting tampering or other malicious, criminal, or terrorist actions
- requesting locked and/or sealed vehicles/containers/railcars and providing the seal number to the consignee
- requesting that the transporter have the capability to verify the location of the load at any time
- establishing scheduled pickups, and not accepting unexplained, unscheduled pickups
- keeping track of finished products
- investigating missing or extra stock or other irregularities outside a normal range of variation and alerting appropriate law enforcement and public health authorities about unresolved problems, when appropriate
- advising sales staff to be on the lookout for counterfeit products and to alert management if any problems are detected

☐ **Mail/packages**

- implementing procedures to ensure the security of incoming mail and packages (for example, locating the mailroom away from food processing and storage areas, securing mailroom, visual or x-ray mail/package screening, following U.S. Postal Service guidance)

☐ **Access to computer systems**

- restricting access to computer process control systems and critical data systems to those with appropriate clearance (for example, using passwords, firewalls)
- eliminating computer access when a staff member is no longer associated with the establishment
- establishing a system of traceability of computer transactions
- reviewing the adequacy of virus protection systems and procedures for backing up critical computer based data systems
- validating the computer security system

Emergency Point of Contact:

U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
301-443-1240

If a food establishment operator suspects that any of his/her products that are regulated by the FDA have been subject to tampering, "counterfeiting," or other malicious, criminal, or terrorist action, FDA recommends that he/she notify the FDA 24-hour emergency number at 301-443-1240 or call their local FDA District Office. FDA District Office telephone numbers are listed at: http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html. FDA recommends that the operator also notify appropriate law enforcement and public health authorities.

*Reference to these documents is provided for informational purposes only. These documents are not incorporated by reference into this guidance and should not be considered to be FDA. ✕ guidance.

U. S. Department of Health and Human Services
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 21, 2003

Guidance for Industry
Retail Food Stores and Food Service Establishments:
Food Security Preventive Measures Guidance
Draft Guidance

This draft guidance represents the Agency's current thinking on the kinds of measures that retail food store and food service establishment operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Purpose and Scope:

This draft guidance is designed as an aid to operators of retail food stores and food service establishments (i.e., bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for home-bound persons, mobile food carts, restaurants, and vending machine operators). This is a very diverse set of establishments, which includes both very large and very small entities.

This draft guidance identifies the kinds of preventive measures they may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. Operators of food retail food stores and food service establishments are encouraged to review their current procedures and controls in light of the potential for tampering or other malicious, criminal, or terrorist actions and make appropriate improvements.

This draft guidance is designed to focus operator's attention sequentially on each segment of the food delivery system that is within their control, to minimize the risk of tampering or other malicious, criminal, or terrorist action at each segment. To be successful, implementing enhanced preventive measures requires the commitment of management and staff. Accordingly, FDA recommends that both management and staff participate in the development and review of such measures.

Limitations:

Not all of the guidance contained in this document may be appropriate or practical for every retail food store or food service establishment, particularly smaller facilities. FDA recommends that operators review the guidance in each section that relates to a component of their operation, and assess which preventive measures are suitable. Example approaches are provided for many of the preventive measures listed in this document. These examples should not be regarded as minimum standards. Nor should the examples provided be considered an inclusive list of all potential approaches to achieving the goal of the preventive measure. FDA recommends that operators consider the goal of the preventive measure, assess whether the goal is relevant to their operation, and, if it is, design an approach that is both efficient and effective to accomplish the goal under their conditions of operation.

Structure:

This draft guidance is divided into five sections that relate to individual components of a retail food store or food service establishment operation: management; human element -- staff; human element -- public; facility; and operations.

Related Guidance:

FDA has published two companion guidance documents on food security, entitled, "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance" to cover the farm-to-table spectrum of food production. Both documents are available at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

Additional Resources:*

A process called Operational Risk Management (ORM) may help prioritize the preventive measures that are most likely to have the greatest impact on reducing the risk of tampering or other malicious, criminal, or terrorist actions against food. Information on ORM is available in the Federal Aviation Administration (FAA) System Safety Handbook, U.S. Department of Transportation, FAA, December 30, 2000, Chapter 15, Operational Risk Management. The handbook is available at: http://www.asy.faa.gov/Risk/SSHandbook/Chap15_1200.PDF.

The U.S. Department of Transportation, Research and Special Programs Administration has published an advisory notice of voluntary measures to enhance the security of hazardous materials shipments. It is available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-3636-filed.pdf. The notice provides guidance to shippers and carriers on personnel, facility and en route security issues.

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The National Infrastructure Protection Center (NIPC) serves as the federal government's focal point for threat assessment, warning, investigation, and response for threats or attacks against U.S. critical infrastructure. The NIPC has identified the food system as one of the eight critical infrastructures, and has established a public-private partnership with the food industry, called the Food Industry Information and Analysis Center (Food Industry ISAC). The NIPC provides the Food Industry ISAC with access, information and analysis, enabling the food industry to report, identify, and reduce its vulnerabilities to malicious attacks, and to recover from such attacks as quickly as possible. In particular, the NIPC identifies credible threats and crafts specific warning messages to the food industry. Further information is available at <http://www.nipc.gov/> and <http://www.foodisac.org/>.

Finally, FDA encourages trade associations to evaluate the preventive measures contained in this guidance document and adapt them to their specific products and operations and to supplement this guidance with additional preventive measures when appropriate. FDA welcomes dialogue on the content of sector specific guidance with appropriate trade associations.

Retail Food Store and Food Service Establishment Operations:

Management

FDA recommends that retail food store and food service establishment operators consider:

- ☐ Preparing for the possibility of tampering or other malicious, criminal, or terrorist events
 - assigning responsibility for security to knowledgeable individual(s)
 - conducting an initial assessment of food security procedures and operations, which we recommend be kept confidential
 - having a crisis management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected products
 - planning for emergency evacuation, including preventing security breaches during evacuation
 - becoming familiar with the emergency response system in the community
 - making management aware of 24-hour contact information for local, state, and federal police/fire/rescue/health/homeland security agencies
 - making staff aware of who in management they should alert about potential security problems (24-hour contacts)
 - promoting food security awareness to encourage all staff to be alert to any signs of tampering or malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and to report any findings to identified management (for example, providing training, instituting a system of rewards, building security into job performance standards)
 - having an internal communication system to inform and update staff about relevant security issues
 - having a strategy for communicating with the public (for example, identifying a media spokesperson, preparing generic press statements and background information, and coordinating press statements with appropriate authorities)
- ☐ Supervision
 - providing an appropriate level of supervision to all staff, including cleaning and maintenance staff, contract workers, data entry and computer support staff, and especially, new staff (for example, supervisor on duty, periodic unannounced visits by supervisor, daily visits by supervisor, two staff on duty at same time, monitored video cameras, off line review of video tapes, one way and two way windows, customer feedback to supervisor of unusual or suspicious behavior by staff)
 - conducting routine security checks of the premises, including utilities and critical computer data systems (at a frequency appropriate to the operation) for signs of tampering or malicious, criminal, or terrorist actions, or areas that may be vulnerable to such actions
- ☐ Investigation of suspicious activity
 - investigating threats or information about signs of tampering or other malicious, criminal, or terrorist actions
 - alerting appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions
- ☐ Evaluation program

- evaluating the lessons learned from past tampering or other malicious, criminal, or terrorist actions and threats
- reviewing and verifying, at least annually, the effectiveness of the security management program (for example, using knowledgeable in-house or third party staff to conduct tampering or other malicious, criminal, or terrorist action exercises and to challenge computer security systems), revising accordingly (using third party or in-house security expert, where possible), revising the program accordingly, and keeping this information confidential
- performing random food security inspections of all appropriate areas of the facility (including receiving and storage areas, where applicable) using knowledgeable in-house or third party staff, and keeping this information confidential
- verifying that security contractors are doing an appropriate job, when applicable

Human element -- staff

Under Federal law, retail food store and food service establishment operators are required to verify the employment eligibility of all new hires, in accordance with the requirements of the Immigration and Nationality Act, by completing the INS Employment Eligibility Verification Form (INS Form I-9). Completion of Form I-9 for new hires is required by 8 USC 1324a and nondiscrimination provisions governing the verification process are set forth at 1324b. FDA recommends that retail food store and food service establishment operators consider:

☐ Screening (pre-hiring, at hiring, post-hiring)

- examining the background of all staff (including seasonal, temporary, contract, and volunteer staff, whether hired directly or through a recruitment firm) as appropriate to their position, considering candidates' access to sensitive areas of the facility and the degree to which they will be supervised and other relevant factors (for example, obtaining and verifying work references, addresses, and phone numbers, participating in one of the pilot programs managed by the Immigration and Naturalization Service and the Social Security Administration [These programs provide electronic confirmation of employment eligibility for newly hired employees. For more information call the INS SAVE Program toll free at 1-888-464-4218, fax a request for information to (202) 514-9981, or write to US/INS, SAVE Program, 425 I Street, NW, ULLICO-4th Floor, Washington, DC 20536. These pilot programs may not be available in all states], having a criminal background check performed by local law enforcement or by a contract service provider [Remember to first consult any state or local laws that may apply to the performance of such checks])
- Note: screening procedures should be applied equally to all staff, regardless of race, national origin, religion, and citizenship or immigration status.

☐ Daily work assignments

- knowing who is and who should be on premises, and where they should be located, for each shift
- keeping information updated

☐ Identification

- establishing a system of positive identification and recognition (for example, issuing uniforms, name tags, or photo identification badges with individual control numbers, color coded by area of authorized access), when appropriate
- collecting the uniforms, name tag, or identification badge when a staff member is no longer associated with the establishment

☐ Restricted access

- identifying staff that require unlimited access to all areas of the facility
- reassessing levels of access for all staff periodically
- limiting staff access to non-public areas so staff enter only those areas necessary for their job functions and only during appropriate work hours (for example, using key cards or keyed or cipher locks for entry to sensitive areas, color coded uniforms [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes])
- changing combinations, rekeying locks and/or collecting the retired key card when a staff member who is in possession of these is no longer associated with the establishment, and additionally as needed to maintain security

☐ Personal items

- restricting the type of personal items allowed in non-public areas of the establishment
- allowing in the non-public areas of the establishment only those personal use medicines that are necessary for the health of staff (other than those being stored or displayed for retail sale) and ensuring that these personal use medicines are properly labeled and stored away from stored food and food preparation areas
- preventing staff from bringing personal items (for example, lunch containers, purses) into nonpublic food preparation or storage areas
- providing for regular inspection of contents of staff lockers (for example, providing metal mesh lockers, company issued locks), bags, packages, and vehicles when on company property (Remember to first consult any federal, state, or local laws that may relate to such inspections)

☐ Training in food security procedures

- incorporating food security awareness, including information on how to prevent, detect, and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including seasonal, temporary, contract, and volunteer staff
- providing periodic reminders of the importance of security procedures (for example, scheduling meetings, providing brochures, payroll stuffers)
- encouraging staff support (for example, involving staff in food security planning and the food security awareness program, demonstrating the importance of security procedures to the staff)
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☐ Unusual behavior

- watching for unusual or suspicious behavior by staff (for example, staff who, without an identifiable purpose, stay unusually late after the end of their shift, arrive unusually early, access files/information/areas of the facility outside of the areas of their responsibility; remove documents from the facility; ask questions on sensitive subjects; bring cameras to work)

☐ Staff health

- being alert for atypical staff health conditions that staff may voluntarily report and absences that could be an early indicator of tampering or other malicious, criminal,

or terrorist actions (for example, an unusual number of staff who work in the same part of the facility reporting similar symptoms within a short time frame), and reporting such conditions to local health authorities

Human element -- public

FDA recommends that retail food store and food service establishment operators consider:

- ☐ Customers
 - preventing access to food preparation and storage and dishwashing areas in the non-public areas of the establishment, including loading docks
 - monitoring public areas, including entrances to public restrooms (for example, using security guards, monitored video cameras, one-way and two-way windows, placement of employee workstations for optimum visibility) for unusual or suspicious activity (for example, a customer returning a product to the shelf that he/she brought into the store, spending an unusual amount of time in one area of the store)
 - monitoring the serving or display of foods in self-service areas (for example, salad bars, condiments, open bulk containers, produce display areas, doughnut/bagel cases)
- ☐ Other visitors (for example, contractors, sales representatives, delivery drivers, couriers, pest control representatives, third-party auditors, regulators, reporters, tours)
 - restricting entry to the non-public areas of the establishment (for example, checking visitors in and out before entering the non-public areas, requiring proof of identity, issuing visitors badges that are collected upon departure, accompanying visitors)
 - ensuring that there is a valid reason for all visits to the non-public areas of the establishment before providing access to the facility - beware of unsolicited visitors
 - verifying the identity of unknown visitors to the non-public areas of the establishment
 - inspecting incoming and outgoing packages and briefcases in the non-public areas of the establishment for suspicious, inappropriate or unusual items, to the extent practical

Facility

FDA recommends that retail food store and food service establishment operators consider:

- ☐ Physical security
 - protecting non-public perimeter access with fencing or other deterrent, when appropriate
 - securing doors (including freight loading doors, when not in use and not being monitored, and emergency exits), windows, roof openings/hatches, vent openings, ventilation systems, utility rooms, ice manufacturing and storage rooms, loft areas and trailer bodies, and bulk storage tanks for liquids, solids and compressed gases to the extent possible (for example, using locks, "jimmy plates," seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes])
 - using metal or metal-clad exterior doors to the extent possible when the facility is not in operation, except where visibility from public thoroughfares is an intended deterrent (remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes)

- minimizing the number of entrances to non-public areas (remember to consult any relevant federal, state or local fire or occupational safety codes before making any changes)
 - accounting for all keys to establishment (for example, assigning responsibility for issuing, tracking, and retrieving keys)
 - monitoring the security of the premises using appropriate methods (for example, using security patrols [uniformed and/or plain-clothed], monitored video surveillance)
 - minimizing, to the extent practical, places in public areas that an intruder could remain unseen after work hours
 - minimizing, to the extent practical, places in non-public areas that can be used to temporarily hide intentional contaminants (for example, minimizing nooks and crannies, false ceilings)
 - providing adequate interior and exterior lighting, including emergency lighting, where appropriate, to facilitate detection of suspicious or unusual activity
 - implementing a system of controlling vehicles authorized to park in the non-public parking areas (for example, using placards, decals, key cards, keyed or cipher locks, issuing passes for specific areas and times to visitors' vehicles)
 - keeping customer, employee and visitor parking areas separated from entrances to non-public areas, where practical
- Storage and use of poisonous and toxic chemicals (for example, cleaning and sanitizing agents, pesticides) in non-public areas
- limiting poisonous and toxic chemicals in the establishment to those that are required for the operation and maintenance of the facility and those that are being stored or displayed for retail sale
 - storing poisonous and toxic chemicals as far away from food handling and food storage areas as practical
 - limiting access to and securing storage areas for poisonous or toxic chemicals that are not being held for retail sale (for example, using keyed or cipher locks, key cards, seals, alarms, intrusion detection sensors, guards, monitored video surveillance [remember to consult any relevant federal, state or local fire codes before making any changes])
 - ensuring that poisonous and toxic chemicals are properly labeled
 - using pesticides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (for example, maintaining rodent bait that is in use in covered, tamper-resistant bait stations)
 - knowing what poisonous and toxic chemicals should be on the premises and keeping track of them
 - investigating missing stock or other irregularities outside a normal range of variation and alerting local enforcement and public health agencies about unresolved problems, when appropriate

Operations

FDA recommends that retail food store and food service establishment operators consider:

- Incoming products
 - using only known and appropriately licensed or permitted (where applicable) sources for all incoming products
 - informing suppliers, distributors and transporters about FDA's food security guidance, "Food producers, processors, and transporters: Food security preventive measures"

guidance" and "Importers and filers: Food security preventive measures guidance," available at: http://www.access.gpo.gov/su_docs/aces/aces140.html.

- taking steps to ensure that delivery vehicles are appropriately secured
- requesting that transporters have the capability to verify the location of the load at any time, when practical
- establishing delivery schedules, not accepting unexplained, unscheduled deliveries or drivers, and investigating delayed or missed shipments
- supervising off-loading of incoming materials, including off hour deliveries
- reconciling the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents, taking into account any sampling performed prior to receipt
- investigating shipping documents with suspicious alterations
- inspecting incoming products and product returns for signs of tampering, contamination or damage (for example, abnormal powders, liquids, stains, or odors, evidence of resealing, compromised tamper-evident packaging) or "counterfeiting" (for example, inappropriate or mismatched product identity, labeling, product lot coding or specifications, absence of tamper-evident packaging when the label contains a tamper-evident notice), when appropriate
- rejecting suspect food
- alerting appropriate law enforcement and public health authorities about evidence of tampering, "counterfeiting," or other malicious, criminal, or terrorist action

□ Storage

- having a system for receiving, storing and handling distressed, damaged, and returned products, and products left at checkout counters, that minimizes their potential for being compromised (for example, obtaining the reason for return and requiring proof of identity of the individual returning the product, examining returned or abandoned items for signs of tampering, not reselling returned or abandoned products)
- keeping track of incoming products, materials in use, salvage products, and returned products
- investigating missing or extra stock or other irregularities outside a normal range of variability and reporting unresolved problems to appropriate law enforcement and public health authorities, when appropriate
- minimizing reuse of containers, shipping packages, cartons, etc., where practical

□ Food service and retail display

- displaying poisonous and toxic chemicals for retail sale in a location where they can be easily monitored (for example, visible by staff at their work stations, windows, video monitoring)
- periodically checking products displayed for retail sale for evidence of tampering or other malicious, criminal, or terrorist action (for example, checking for off-condition appearance [for example, stained, leaking, damaged packages, missing or mismatched labels], proper stock rotation, evidence of resealing, condition of tamper-evident packaging, where applicable, presence of empty food packaging or other debris on the shelving), to the extent practical
- monitoring self-service areas (for example, salad bars, condiments, open bulk containers, produce display areas, doughnut/bagel cases) for evidence of tampering or other malicious, criminal, or terrorist action

□ Security of water and utilities

- limiting to the extent practical access to controls for airflow, water, electricity, and refrigeration
- securing non-municipal water wells, hydrants, storage and handling facilities
- ensuring that water systems and trucks are equipped with backflow prevention
 - ☐ chlorinating non-municipal water systems and monitoring chlorination equipment and chlorine levels
 - ☐ testing non-municipal sources for potability regularly, as well as randomly, and being alert to changes in the profile of the results
 - ☐ staying attentive to the potential for media alerts about public water provider problems, when applicable
- identifying alternate sources of potable water for use during emergency situations where normal water systems have been compromised (for example, bottled water, trucking from an approved source, treating on-site or maintaining on-site storage)
- ☐ Mail/packages
 - implementing procedures to ensure the security of incoming mail and packages
- ☐ Access to computer systems
 - restricting access to critical computer data systems to those with appropriate clearance (for example, using passwords, firewalls)
 - eliminating computer access when a staff member is no longer associated with the establishment
 - establishing a system of traceability of computer transactions
 - reviewing the adequacy of virus protection systems and procedures for backing up critical computer based data systems
 - validating the computer security system

Emergency Point of Contact:

U.S. Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857
 301-443-1240

If a retail food store or food service establishment operator suspects that any of his/her products that are regulated by the FDA have been subject to tampering, "counterfeiting," or other malicious, criminal, or terrorist action, FDA recommends that he/she notify the FDA 24-hour emergency number at 301-443-1240 or call their local FDA District Office. FDA recommends that the operator also notify local law enforcement and public health authorities.

FDA District Office telephone numbers are listed at: http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html.

*Reference to these documents is provided for informational purposes only. These documents are not incorporated by reference into this guidance and should not be considered to be FDA guidance. ❧

FOODBORNE ILLNESS: WHAT IS IT AND HOW TO REPORT IT

What is foodborne illness?

Foodborne illness is commonly known as food poisoning. It occurs when someone becomes ill after eating a food or beverage that is contaminated with a harmful substance.

Is foodborne illness a significant problem?

The Centers for Disease Control and Prevention estimate that there are 76,000,000 cases of foodborne illness in the United States each year. While most cases result in no serious illness or injury, there are an estimated 325,000 hospitalizations and 5,000 deaths every year. Even the non-serious illnesses, however, can result in much discomfort, inconvenience and financial loss.

What causes foodborne illness?

Not all foodborne illnesses are the same. Foodborne illness can occur when food becomes contaminated with harmful substances such as bacteria, viruses, parasites, natural toxins and chemicals. Some of these substances can cause illness within minutes, while others may take several hours, days or even weeks to make someone sick. Therefore, it is not always the last thing eaten which causes an illness. The bad food may actually have been eaten several days before the illness began.

What are the symptoms of foodborne illness?

The most common symptoms of foodborne illness are vomiting and/or diarrhea. Nausea and stomach cramps are also common. Fever, headache, chills, muscle aches and dizziness may also occur. In fact, if you experience vomiting or diarrhea, foodborne illness is always a possibility, although it is not the only cause of such symptoms. Foodborne illness can also cause unusual symptoms such as irregular heartbeat, flushing of the skin, paralysis, and difficulty breathing. If someone you shared a meal with is having similar symptoms at the same time that you are, it is even more likely that you are both suffering from a foodborne illness.

What should I do if I suspect I have a foodborne illness?

You should consult a doctor for advice on whether medical treatment is needed. Many foodborne illnesses are relatively short-lived. Many people will get better without treatment. However, it is always advisable to consult a doctor if you have any concerns about the seriousness of your illness. Young children, the elderly and immunocompromised people are more likely than others to experience severe illness. If you do see a doctor, you may be asked to provide a stool sample for testing. For many foodborne illnesses, a stool test is needed to confirm the diagnosis. As soon as you can, you should call your local board of health or the Massachusetts Department of Public Health to report the suspect foodborne illness.

How do I report a foodborne illness?

If you think you or someone you know has experienced a foodborne illness, there are several ways you can report the incident. You can call:

- ☐ the local board of health in the town in which the suspect food was eaten or purchased, or
- ☐ the local board of health in the town in which you live, (You can find phone numbers of local boards of health at www.mhoa.com or in the phone book) or
- ☐ the Massachusetts Department of Public Health's Division of Food and Drugs at 617-983-6712, or
- ☐ the Massachusetts Department of Public Health's Division of Epidemiology and Immunization at 617-983-6800.

Be prepared to answer some questions. The interview may take as long as 10-15 minutes to complete. You will be asked to give as many details as you can about the ill person(s) and what they ate during the **72 hours** before getting ill. A 72-hour food history is important. It is not always the last thing you ate that made you ill. Many of the substances that cause foodborne illness take several days to cause illness. For example, Salmonella bacteria typically take 12 to 72 hours to make you ill. You will also be asked to describe the symptoms you experienced. You will be asked about the time the symptoms started, how long they lasted and whether a doctor was seen. You may also be asked about recent travel, pet ownership and exposure to drinking and recreational water. ***Note: If you have questions or concerns about your health you should contact a doctor.***

Do I need to give my name?

You will be asked to give your name and the names, addresses and phone numbers of all the ill people as well. You do not have to give out any names if you do not wish to. The more information you provide the easier it is for health agents to do the necessary follow-up. ***All information you give will be kept strictly confidential.*** The information will only be shared with public health officials who are conducting the follow-up investigation. Identities of ill people will not be disclosed to the food establishment or anyone else without permission.

What is the role of the health departments in preventing foodborne illness?

The Massachusetts Department of Public Health works with federal agencies and 336 local health departments to ensure a safe food supply for Massachusetts. Health agents and food inspectors work to protect the food supply by enforcing food safety regulations through regular inspections and investigations of complaints.

In addition, health departments track reports of suspect foodborne illness and reports of confirmed foodborne illnesses. Confirmed illnesses are those in which a person has visited a doctor and has tested positive for a foodborne disease agent. The state health department reviews such reports regularly to look for patterns and groups of complaints and/or illness. If a pattern is found, an investigation is begun. The goal is to identify the source of the illnesses so that the necessary steps can be taken to stop the contamination and prevent more cases of illness.

How is my complaint followed-up?

The local health department in the town in which you purchased the suspect food is responsible for following-up on the complaint. A health agent will review the 72-hour food history that you provided. If the information you give points to an establishment, the health inspector from that town will start an investigation. The inspector will visit the food establishment and review food handling practices including how the foods you ate were prepared.

If many people have reported being ill after eating at a particular establishment or eating a particular food then a larger investigation is begun. Investigators from the state health department will often assist the local health agents. They work with the local health agents to uncover the causes of outbreaks and put in place procedures to prevent future outbreaks. The investigation of larger outbreaks may include collecting stool samples for testing from employees and ill patrons. Food samples may also be collected for analysis. Sometimes a food history questionnaire is sent out to patrons and employees to help determine which food(s) made people ill.

What should I do if I have any of the suspect food left over?

If there is suspect food left over, it should be stored in the refrigerator. It should be kept in the original container. If that is not possible, put it into a clean container or plastic bag. Make sure everyone in the household knows *not* to eat the suspect food. When you report the illness to the health department, report that there is left over food. ***Not all food samples will be analyzed by the health department.***

Where can I get more information?

For additional information on foodborne illness see the following information from the Food and Drug Administration:

- ☐ FDA's Bad Bug Book: <http://vm.cfsan.fda.gov/~mow/intro.html>
- ☐ FDA's The Unwelcome Dinner Guest: Preventing Foodborne Illness: <http://www.cfsan.fda.gov/~dms/fdunwelc.html>
- ☐ FDA's Foodborne Illness page: <http://www.cfsan.fda.gov/~mow/foodborn.html>

Or visit the Massachusetts Department of Public Health's website on Foodborne Illness Information at <http://www.state.ma.us/dph/fpp/retail/Safety.htm> ☒

January 2003

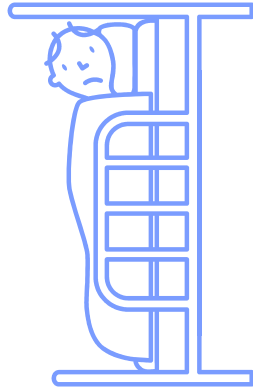
Notes

What is foodborne illness?

Foodborne commonly food

It occurs someone after eating beverage

illness is known as poisoning, when becomes ill a food or that is



contaminated with a harmful germ or substance.

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Not all foodborne illnesses are the same. Foodborne illness can occur when food becomes contaminated with harmful bacteria, viruses, parasites, natural toxins and chemicals. Some of these can cause illness within minutes, while others may take several hours, days or even weeks to make someone sick. Therefore, it is not always the last thing eaten which causes an illness. The bad food may actually have been eaten several days before the illness began.

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To Report a Suspect Foodborne Illness, call

Your Local Health Department
or

The Division of Food and Drugs
Food Protection Program
617-983-6712
or

The Division of Epidemiology and
Immunization
617-983-6800

Mitt Romney
Governor

Kerry Healey
Lieutenant Governor

Ronald Preston
Secretary

Christine C. Ferguson
Commissioner
Department of Public Health

Foodborne Illness



What is it? How to report it

Massachusetts
Department of Public Health

Division of Food and Drugs
Food Protection Program
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Division of Epidemiology and Immunization
617-983-6800

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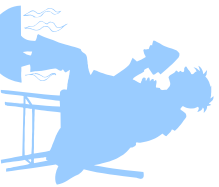


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foodborne illness?

You should consult a health care provider for advice on whether medical treatment is needed.

Many foodborne illnesses are relatively short-lived and people get better without treatment. Young children, the elderly and immunocompromised people are more likely than others to experience severe illness. If you do see a doctor or other practitioner you may be asked to provide a stool sample for testing. For many foodborne illnesses, a stool test is needed to confirm the diagnosis. As soon as you can, you should call your local board of health or the Massachusetts Department of Public Health to report the suspect foodborne illness.



Be prepared to answer some questions.

You will be interviewed. The interview may take as long as 10 to 15 minutes. You will be asked to give as many details as you can about the ill person(s) and what they ate during the **72 hours** before getting ill. A 72 hour food history is important.

How do I report a foodborne illness?

If you think you or someone you know has experienced a foodborne illness, there are several ways you can report the incident.

You can call:

- ❖ the local board of health in the town in which the suspect food was eaten or purchased
- or
- ❖ the local board of health in the town in which you live (You can find phone numbers of local boards of health at www.mhoa.com or in the phone book)
- or
- ❖ the Massachusetts Department of Public Health's Division of Food and Drugs at 617-983-6712
- or
- ❖ the Massachusetts Department of Public Health's Division of Epidemiology and Immunization at 617-983-6800

It is not always the last thing you ate that made you ill. For example, *Salmonella* bacteria typically take 12 to 72 hours to make you ill. You will also be asked to describe the symptoms you experienced. You will be asked about the time the symptoms started, how long they lasted and whether you received health care.



You may also be asked about recent travel, pet ownership and exposure to drinking and recreational water.

Do I need to give my name?

You will be asked to give your name and the names, addresses and phone numbers of all the ill people as well. You do not have to give out any names. However, the more information you provide the easier it is for health agents to do the necessary follow-up. **All information will be kept strictly confidential** and only shared with public health officials who are conducting the follow-up investigation. Identities of ill people will not be disclosed to the food establishment or anyone else, without permission.

What should I do if I have any of the suspect food left over?

If there is suspect food left over, it should be stored in the refrigerator. It should be kept in the original container. If that is not possible, put it into a clean container or plastic bag. Make sure everyone in the household knows *not* to eat the suspect food. When you report the illness to the health department, report that there is left over food. *Not all food samples will be analyzed by the health department.*

What should I do if I suspect I have a

Outbreaks of Gastroenteritis Associated with Noroviruses on Cruise Ships --- United States, 2002

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5149a2.htm>

Vol 51, No 49;1112 12/13/2002

Morbidity and Mortality Weekly Report (MMWR)

Centers for Disease Control and Prevention

Atlanta, Georgia: U.S. Department of Health and Human Services, CDC, 2000

During January 1--December 2, 2002, CDC's Vessel Sanitation Program (VSP), which conducts surveillance for acute gastroenteritis (AGE) on cruise ships with foreign itineraries sailing into U.S. ports, received reports of 21 outbreaks of AGE* on 17 cruise ships. Of the 21 outbreaks, nine were confirmed by laboratory analysis of stool specimens from affected persons to be associated with noroviruses, three were attributable to bacterial agents, and nine were of unknown etiology. Seven outbreaks were reported in 2001, and of these, four were confirmed to be associated with norovirus (CDC, unpublished data, 2002). This report describes five of the norovirus outbreaks that occurred during July 1-December 2, 2002, on cruise ships.

Outbreaks

Cruise Ship A. On July 18, cruise ship A, owned by cruise line A, embarked 1318 passengers and 564 crew members for a 7-day cruise from Vancouver to Alaska. On July 19, five passengers reported to the ship's infirmary with symptoms of AGE. By July 25, a total of 167 (13%) passengers and nine (2%) crew members had reported illness. Among the 176 patients, the predominant symptoms were vomiting (76%) and diarrhea (73%). Five of 10 stool specimens from ill passengers were positive for norovirus by reverse transcriptase polymerase chain reaction (RT-PCR). On July 25, when passengers disembarked, the ship was disinfected in accordance with CDC recommendations, and the same day, a new group of passengers embarked for another 7-day cruise. During the cruise, 189 (14%) of 1336 passengers and 30 (5.3%) of 571 crew members had AGE with diarrhea (91%) and vomiting (85%). An environmental health inspection conducted by CDC revealed no sanitary deficiencies. Cruise line A cancelled a subsequent cruise and voluntarily took the ship out of service for 1 week for aggressive cleaning and sanitizing. No outbreaks were reported on subsequent cruises.

Cruise Ship B. On October 1, cruise ship B, also owned by cruise line A, embarked 1,281 passengers and 598 crew members for a 21-day cruise from Washington to Florida. By October 16, a total of 101 (8%) passengers and 14 (2%) crew members reported to the infirmary with AGE symptoms. On October 18, CDC investigators boarded the ship to conduct an epidemiologic and environmental investigation. Of 972 surveyed passengers, 399 (41%) met the case definition for AGE. Investigators found no association between illness and water, specific meals served on the ship, or with offshore excursions. Stool specimens from 12 of 13 patients tested positive for norovirus. Characterization of the strain by sequence analysis of RT-PCR products matched those from cruise ship A. Despite implementation of control measures that included disinfection of the vessel and quarantine of ill passengers and crew members, a total of 264 passengers and 41 crew members reported illness on three subsequent 10-day cruises. Cruise line A voluntarily withdrew cruise ship B from service for 10 days for aggressive cleaning and sanitizing. No outbreaks were reported on subsequent voyages.

Cruise Ship C. On September 28, cruise ship C, owned by cruise line B, embarked 1984 passengers and 941 crew members for a 7-day round-trip cruise from Florida to the Caribbean. Several passengers had AGE within 24 hours of embarkation, and by October 1, a total of 70 (4%) passengers and two (0.2%) crew members reported illness. On October 3, CDC investigators boarded the ship to conduct an epidemiologic and environmental investigation. Questionnaires completed by 1,879 (95%) passengers and 860 (91%) crew members identified 356 (19%) passengers and 13 (1.5%) crew members who met the AGE case definition. The epidemiologic investigation suggested a point source of infection, followed by cases associated with person-to-person transmission. The investigation identified an association between illness among passengers and lunch served at embarkation (odds ratio=2.4; 95% confidence interval=1.1--5.2; p value=0.02). Four of 11 stool specimens from patients were positive for norovirus by RT-PCR. Characterization of the strain by sequence analysis of RT-PCR products matched those from an outbreak on the same ship that occurred 3 weeks previously but was not identical to the outbreak strain on cruise ships A and B. CDC recommended reinforcing sanitation practices and excluding ill foodhandlers from the work place. Cruise ship C continued service, and no new cases were reported on subsequent cruises.

Cruise Ship D. On October 25, cruise ship D, owned by cruise line C, embarked 2,882 passengers and 944 crew members in Spain for a 14-day cruise to Florida. On October 28, a total of 70 (2.5%) passengers reported to the infirmary with AGE; the number of ill passengers declined rapidly during the following days. By November 2, a total of 106 (5%) passengers and 25 (3%) crew members had reported illness. Stool specimens from four of six patients tested positive for norovirus by RT-PCR. Characterization of the strain by sequence analysis of RT-PCR products identified a strain distinct from the other cruise-ship outbreaks. With passengers aboard, control measures included quarantine of ill crew members until symptom-free for 72 hours, disinfection of the ship, and reinforcement of sanitation practices. No new outbreaks were reported on subsequent cruises.

Cruise Ship E. On November 16, cruise ship E, owned by cruise line D, embarked 2318 passengers and 988 crew members for a 7-day cruise from Florida to the Caribbean. By November 20, a total of 28 (1%) passengers and seven (1%) crew members had reported to the ship's infirmary with AGE. By disembarkation on November 23, a total of 260 (12%) passengers and 17 (2%) crew members had reported illness. On November 23, CDC investigators boarded the ship and collected questionnaires that had been distributed to all passengers before disembarkation. A total of 1280 (55%) passengers returned a questionnaire; of these, 492 (21%) met the case definition for AGE. Seven of 12 specimens from patients were positive for norovirus by RT-PCR. Characterization of the strain by sequence analysis of RT-PCR products identified a perfect match with those products from the outbreaks on cruise ships A and B. Despite implementation of disinfection and sanitation measures, the outbreak continued on the subsequent cruise. On November 30, cruise line D removed the ship from service for 1 week for aggressive cleaning and sanitizing.

Reported by: EH Cramer, MD, D Forney, Vessel Sanitation Program; AL Dannenberg, MD, Div of Emergency and Environmental Health Svcs, National Center for Environmental Health; MA Widdowson, VetMB, JS Bresee, MD, S Monroe, PhD, RS Beard, H White, MS, S Bulens, MPH, Div of Viral and Rickettsial Diseases; E Mintz, MD, C Stover, MPH, Div of Bacterial Diseases, National Center of Infectious Diseases; E Isakbaeva, MD, J Mullins, DVM, J Wright, DVM, V Hsu, MD, W Chege, MD, J Varma, MD, EIS officers, CDC.

Editorial Note:

Cruise-ship outbreaks demonstrate how easily noroviruses can be transmitted from person to person in a closed environment, resulting in large outbreaks. The continuation of these outbreaks on consecutive cruises with new passengers and the resurgence of outbreaks caused by the same virus strains during previous cruises on the same ship, or even on different ships of the same company, suggests that environmental contamination and infected crew members can serve as reservoirs of infection for passengers.

The increase in reported norovirus outbreaks on cruise ships in 2002 might reflect an actual increase in norovirus outbreaks or it might be attributable to improved surveillance with an electronic reporting format implemented January 1, 2001, and increased application of sensitive molecular assays. The surveillance system captures cases of illness reported to the ship's infirmary or to designated staff on board the ship. Other cases of AGE among passengers and crew members are not reported. In 2002, CDC has confirmed 26 land-based outbreaks of AGE attributable to norovirus; three were caused by strains closely related to the strain detected from cruise ships A, B, and E. Although several land-based outbreaks are linked to norovirus strains with unique sequence types, strains with identical sequence types are identified commonly in outbreaks with no obvious epidemiologic link. Further genetic characterization of common outbreak strains associated with epidemiologic data might help establish possible links among these outbreaks.

Noroviruses (i.e., Norwalk-like viruses or NLV) are members of the family *Caliciviridae* and are well-recognized etiologic agents of nonbacterial AGE. Noroviruses cause approximately 23 million cases of AGE each year and are the leading cause of outbreaks of gastroenteritis. Illness caused by norovirus infection lasts 12-60 hours and is characterized by sudden onset of nausea, vomiting, and watery diarrhea; the incubation period is 12-48 hours. The virus is transmitted by hands contaminated through the fecal-oral route, directly from person to person, through contaminated food or water, or by contact with contaminated surfaces or fomites. Aerosolized vomitus also has been implicated as a transmission mode. Because of high infectivity and persistence in the environment, transmission of noroviruses is difficult to control through routine sanitary measures. Although norovirus causes a self-limited AGE, elderly passengers, children, and those with severe underlying medical conditions might be at increased risk for complications because of volume depletion and electrolyte disturbances. Hospitalization of adults with norovirus who are otherwise healthy is rare. Neither specific antiviral treatment nor a vaccine has been developed for noroviruses.

In addition to emphasizing basic food and water sanitation measures, control efforts should include thorough and prompt disinfection of ships during cruises, and isolation of ill crew members and, if possible, passengers for 72 hours after clinical recovery. Suitable disinfectants include freshly prepared chlorine solutions at concentrations of $\geq 1,000$ ppm, phenol-based compounds, and accelerated hydrogenperoxide products. Cruise ships also should promote frequent, rigorous hand washing with soap and water by passengers and crew members.

Rapid implementation of control measures at the first sign of a suspected AGE outbreak is critical in preventing additional cases. When routine disinfection measures are unsuccessful at interrupting the spread of virus during an outbreak, more extensive disinfection and a period of time without passengers aboard a ship might facilitate elimination of the virus.

CDC encourages local and state health departments to test for noroviruses when investigating outbreaks of suspected viral AGE. For assistance in testing for noroviruses and for strain characterization, local and state health departments should contact CDC's Viral Gastroenteritis Section, telephone 404-639-3577 or by e-mail: CaliciNet@cdc.gov.

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* An outbreak of AGE was defined as one in which $\geq 3\%$ of passengers or crew members report illness (defined as three or more episodes of loose stools in a 24-hour period or as vomiting with one additional symptom such as abdominal cramps, headache, myalgia, or fever). The evaluation of an outbreak might consist of environmental, epidemiologic, and laboratory investigative components, including an epidemic survey distributed to passengers and crew members, environmental sampling, and collection of stool specimens from patients. ✕

Norovirus: Technical Fact Sheet

<http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-factsheet.htm>

Centers for Disease Control and Prevention

Atlanta, Georgia: U.S. Department of Health and Human Services, CDC, 2000.

Noroviruses (genus *Norovirus*, family *Caliciviridae*) are a group of related, single-stranded RNA, nonenveloped viruses that cause acute gastroenteritis in humans. Norovirus was recently approved as the official genus name for the group of viruses provisionally described as “Norwalk-like viruses” (NLV). This group of viruses has also referred to as caliciviruses (because of their virus family name) and as small round structured viruses, or SRSVs (because of their morphologic features). Another genus of the calicivirus family that can cause gastroenteritis in humans is *Sapovirus*, formerly described as “Sapporo-like virus” (SLV) and sometimes referred to as classic or typical calicivirus.

Noroviruses are named after the original strain “Norwalk virus,” which caused an outbreak of gastroenteritis in a school in Norwalk, Ohio, in 1968. Currently, there are at least four norovirus genogroups (GI, GII, GIII and GIV), which in turn are divided into at least 20 genetic clusters.

Clinical Presentation

The incubation period for norovirus-associated gastroenteritis in humans is usually between 24 and 48 hours (median in outbreaks 33 to 36 hours), but cases can occur within 12 hours of exposure. Norovirus infection usually presents as acute-onset vomiting, watery non-bloody diarrhea with abdominal cramps, and nausea. Low-grade fever also occasionally occurs, and vomiting is more common in children. Dehydration is the most common complication, especially among the young and elderly, and may require medical attention. Symptoms usually last 24 to 60 hours. Recovery is usually complete and there is no evidence of any serious long-term sequelae. Studies with volunteers given stool filtrates have shown that asymptomatic infection may occur in as many as 30% of infections, although the role of asymptomatic infection in norovirus transmission is not well understood.

Virus Transmission

Noroviruses are transmitted primarily through the fecal-oral route, either by consumption of fecally contaminated food or water or by direct person-to-person spread. Environmental and fomite contamination may also act as a source of infection. Good evidence exists for transmission due to aerosolization of vomitus that presumably results in droplets contaminating surfaces or entering the oral mucosa and being swallowed. No evidence suggests that infection occurs through the respiratory system.

Noroviruses are highly contagious, and it is thought that an inoculum of as few as 10 viral particles may be sufficient to infect an individual. During outbreaks of norovirus gastroenteritis, several modes of transmission have been documented; for example, initial foodborne transmission in a restaurant, followed by secondary person-to-person transmission to household contacts. Although presymptomatic viral shedding may occur, shedding usually begins with onset of symptoms and may continue for 2 weeks after recovery. It is unclear to what extent viral shedding over 72 hours after recovery signifies continued infectivity.

Immunity to Norovirus

Mechanisms of immunity to norovirus are unclear. It appears that immunity may be strain-specific and lasts only a few months; therefore, given the genetic variability of noroviruses, individuals are likely to be repeatedly infected throughout their lifetimes. This may explain the

high attack rates in all ages reported in outbreaks. Recent evidence also suggests that susceptibility to infection may be genetically determined, with people of O blood group being at greatest risk for severe infection.

Disease burden of Norovirus Gastroenteritis

CDC estimates that 23 million cases of acute gastroenteritis are due to norovirus infection, and it is now thought that at least 50% of all foodborne outbreaks of gastroenteritis can be attributed to noroviruses.

Among the 232 outbreaks of norovirus illness reported to CDC from July 1997 to June 2000, 57% were foodborne, 16% were due to person-to-person spread, and 3% were waterborne; in 23% of outbreaks, the cause of transmission was not determined. In this study, common settings for outbreaks include restaurants and catered meals (36%), nursing homes (23%), schools (13%), and vacation settings or cruise ships (10%).

Most foodborne outbreaks of norovirus illness are likely to arise through direct contamination of food by a food handler immediately before its consumption. Outbreaks have frequently been associated with consumption of cold foods, including various salads, sandwiches, and bakery products. Liquid items (e.g., salad dressing or cake icing) that allow virus to mix evenly are often implicated as a cause of outbreaks. Food can also be contaminated at its source, and oysters from contaminated waters have been associated with widespread outbreaks of gastroenteritis. Other foods, including raspberries and salads, have been contaminated before widespread distribution and subsequently caused extensive outbreaks.

Waterborne outbreaks of norovirus disease in community settings have often been caused by sewage contamination of wells and recreational water.

Diagnosis of Norovirus

Human. In the last 10 years, diagnosis of norovirus illness in outbreaks has improved with the increasing use of reverse transcriptase polymerase chain reaction (RT-PCR). Currently, 27 state public health laboratories have the capability to test for noroviruses by RT-PCR. RT-PCR can be used to test stool and emesis samples, as well as to detect the presence of noroviruses on environmental swabs in special studies. Identification of the virus can be best made from stool specimens taken within 48 to 72 hours after onset of symptoms, although good results can be obtained by using RT-PCR on samples taken as long as 5 days after symptom onset. Virus can sometimes be found in stool samples taken as late as 2 weeks after recovery.

Older methods for diagnosis include direct and immune electron microscopy of fecal specimens, and detection of a fourfold increase of specific antibodies in acute- and convalescent-phase blood samples. An enzyme-linked immunosorbent assay for detection of virus in stools is under development.

Sequencing of noroviruses found in clinical samples has helped in conducting epidemiologic investigations by linking cases to each other and to a common source and by differentiating outbreaks that were mistakenly connected. Sequences can be entered into CaliciNet, a database used to store the different sequences of norovirus that cause disease throughout the United States, thereby allowing rapid assessment of the relationships between strains.

In addition to microbiological techniques, several epidemiologic criteria have been proposed for use in determining whether an outbreak of gastroenteritis is of viral origin. Kaplan's criteria for

this purpose are as follows: 1) a mean (or median) illness duration of 12 to 60 hours, 2) a mean (or median) incubation period of 24 to 48 hours, 3) more than 50% of people with vomiting, and 4) no bacterial agent previously found. Although quite specific, these criteria are not very sensitive, and therefore the possibility of a viral etiology should not be discarded if the criteria are not met.

Environmental. Assays to detect virus in food need to be adapted for each food substance; these have been only rarely used, with the exception of assays to detect virus in shellfish. Water can be tested for noroviruses by using RT-PCR to detect virus when large volumes of water are processed through specially designed filters.

Management of Norovirus Infection

No specific therapy exists for viral gastroenteritis. Symptomatic therapy consists of replacing fluid losses and correcting electrolyte disturbances through oral and intravenous fluid administration.

Prevention

Prevention of foodborne norovirus disease is based on the provision of safe food and water. Noroviruses are relatively resistant to environmental challenge: they are able to survive freezing, temperatures as high as 60°C, and have even been associated with illness after being steamed in shellfish. Moreover, noroviruses can survive in up to 10 ppm chlorine, well in excess of levels routinely present in public water systems. Despite these features, it is likely that relatively simple measures, such as correct handling of cold foods, frequent handwashing, and paid sick leave, may substantially reduce foodborne transmission of noroviruses.

Surveillance of Norovirus Infection in the United States

CDC currently does not conduct active surveillance to monitor outbreaks of gastroenteritis caused by noroviruses. Outbreaks are reported to CDC's Viral Gastroenteritis Section, Respiratory and Enteric Viruses Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases (NCID) when states send specimens for testing or sequencing, or outbreaks are reported directly by states to the database maintained by the Foodborne Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, NCID.

Recently, a system called CaliciNet has been developed on the basis of the PulseNet model. CaliciNet is a database of norovirus sequences identified from outbreaks of norovirus that can then help to determine links between outbreaks.

For further details please email calicinet@cdc.gov ✕

Notes

Norovirus: Food Handlers

<http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-foodhandlers.htm>

Centers for Disease Control and Prevention

Atlanta, Georgia: U.S. Department of Health and Human Services, CDC, 2000.

What are noroviruses?

Noroviruses are members of a group of viruses called caliciviruses also known previously as “Norwalk-like viruses.” Infection with norovirus affects the stomach and intestines, causing an illness called gastroenteritis, or “stomach flu.” This “stomach flu” is *not* related to the flu (or influenza), which is a respiratory illness caused by influenza virus. In addition, noroviruses are not related to bacteria and parasites that can cause gastrointestinal illnesses. Norovirus is not a “new” virus, but interest in it is growing as more is learned about how frequently noroviruses cause illness in people).

What are the symptoms of infection with norovirus?

Norovirus infection causes gastroenteritis, which is an inflammation of the stomach and the small and large intestines. The symptoms of gastroenteritis are nausea, vomiting, and/or diarrhea accompanied by abdominal cramps. Some people also complain of headache, fever/chills, and muscle aches. Symptoms are usually brief and last only 1 or 2 days. However, during that brief period, people can feel very ill and vomit, often violently and without warning, many times a day. Symptoms usually begin 24 to 48 hours after ingestion of the virus, but can appear as early as 12 hours after exposure. There is no evidence that sick persons can become long-term carriers of the virus, but the virus can be in the stool and vomit of infected persons, from the day they start to feel ill to as long as 2 weeks after they feel better.

Other infectious and non-infectious agents can cause symptoms similar to those of norovirus gastroenteritis; people who have these symptoms and have questions about the cause of their illness should consult a physician.

How serious is norovirus gastroenteritis?

Norovirus gastroenteritis is usually not a serious illness, and other than drinking liquids to prevent dehydration, there is no specific treatment. Most people recover completely within 1 to 2 days, with no long-term complications of norovirus illness. However, persons who are unable to drink enough liquids to replace those lost with vomiting and/or diarrhea may become dehydrated and require special medical attention. These people include young children, the elderly, and persons of any age unable to care for themselves.

How is norovirus spread?

Noroviruses are found in the stool or vomit of infected people. People can become infected with the virus in several ways, including:

- eating food or drinking liquids that are contaminated with norovirus;
- touching surfaces or objects contaminated with norovirus, and then placing their hand in their mouth;
- having direct contact with another person who is infected and showing symptoms (for example, when caring for someone with illness, or sharing foods or eating utensils with someone who is ill).
-

Food and drinks can very easily become contaminated with norovirus because the virus is so small and because it probably takes fewer than 100 norovirus particles to make a person sick. Food can be contaminated either by direct contact with contaminated hands or work surfaces that

are contaminated with stool or vomit, or by tiny droplets from nearby vomit that can travel through air to land on food. Although the virus cannot multiply outside of human bodies, once on food or in water, it can cause illness.

Some foods can be contaminated with norovirus *before* being delivered to a restaurant or store. Several outbreaks have been caused by the consumption of oysters harvested from contaminated waters. Other produce such as salads and frozen fruit may also be contaminated at source.

Why is norovirus infection important for food handlers?

People working with food who are sick with norovirus gastroenteritis are a particular risk to others, because they handle the food and drink many other people will consume. Since the virus is so small, a sick food handler can easily – without meaning to – contaminate the food he or she is handling. Many of those eating the contaminated food may become ill, causing an outbreak.

Outbreaks of norovirus gastroenteritis have taken place in restaurants, cruise ships, nursing homes, hospitals, schools, banquet halls, summer camps, and family dinners – in other words, places where often people have consumed water and/or food prepared or handled by others. It is estimated that as many as half of all food-related outbreaks of illness may be caused by norovirus. In many of these cases, sick food handlers were thought to be implicated.

What can I do to prevent norovirus gastroenteritis?

Many local and state health departments require that food handlers and preparers with gastroenteritis *not* work until 2 or 3 days after they feel better. In addition, because the virus continues to be present in the stool for as long as 2 to 3 weeks after the person feels better, strict hand washing after using the bathroom and before handling food items is important in preventing the spread of this virus. Food handlers who were recently sick can be given different duties in the restaurant so that they do not have to handle food (for example, working the cash register or hostessing).

People who are sick with norovirus illness can often vomit violently, without warning, and the vomit is infectious; therefore, any surfaces near the vomit should be promptly cleaned and disinfected with bleach solution and then rinsed. Furthermore, food items that may have become contaminated with norovirus should be thrown out. Linens (including clothes, towels, tablecloths, napkins) soiled to any extent with vomit or stool should be promptly washed at high temperature. Oysters should be obtained from reputable sources and appropriate documentation kept. Washing raw vegetables thoroughly before eating and appropriate disposal of sewage and soiled diapers also help to reduce the spread of norovirus and prevent illness. In small home-based catering businesses or family owned or operated restaurants, sick children and infants in diapers should be excluded from food preparation areas.

How is norovirus gastroenteritis diagnosed?

In special cases, when there is an outbreak of gastroenteritis there is a need to **identify** norovirus as the cause of the illness. In these cases, norovirus can often be found in stool samples of infected persons by using special tests. Sometimes blood tests looking for antibodies against norovirus are also performed, when the stool tests are inconclusive or were not done. Food handlers will often be asked for a stool sample or even a blood sample to help investigate the cause of an outbreak.

Can a person have norovirus gastroenteritis more than once?

Yes, a person can be infected with norovirus more than once in their lifetime. This is because there are many different noroviruses, and being infected with one type does not prevent infection from another type later. For this reason, it is difficult to develop a vaccine against norovirus. ✕

Hand Hygiene in Retail and Food Service Establishments

FDA FACT SHEET

ON HAND HYGIENE IN RETAIL & FOOD SERVICE ESTABLISHMENTS

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are working together to control the transmission of pathogens that can result in foodborne illnesses. Transmission of pathogenic bacteria, viruses and parasites from raw food or from ill workers to food by way of improperly washed hands continues to be one of several major factors in the spread of foodborne illnesses.

FDA's Food Code contains the Federal recommendations for preventing foodborne illness in restaurants, grocery stores, institutions and vending locations. Local, state and federal regulators use the FDA Food Code as a model to help develop or update their own food safety rules and to be consistent with national food regulatory policy. The Food Code contains specific hand hygiene guidance for retail and food service workers describing when, where, and how to wash and sanitize hands. Hand sanitizers, meeting specific criteria described in section 2-301.16 of the Food Code, may be used after proper hand washing in retail and food service.

CAN ALCOHOL-BASED HAND GELS SERVE AS A SUITABLE ALTERNATIVE TO HANDWASHING FOR RETAIL AND FOOD SERVICE WORKERS?

CDC recently issued "CDC Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Reports, October 25, 2002). The guidance document recommends alcohol-based hand gel as a suitable alternative to handwashing for health-care personnel in health-care settings. These guidelines were not intended to apply to food establishments. This exclusion is based on the differences in controlling common nosocomial pathogens in health-care settings and common foodborne pathogens in retail and food service settings. Some significant differences between health-care settings and retail/ food service settings include:

1. TYPES OF PATHOGENS

The pathogens most commonly transmitted by hands in health-care settings differ from those in retail and foodservice settings. In health-care, nosocomial bacterial pathogens and lipophilic viruses predominate, while in food service and retail establishments we are primarily concerned with a different set of fecal pathogens. Common nosocomial pathogens are typically transmitted from person-to-person in health-care settings. In retail and food service settings, foodborne pathogens are transmitted through the fecal-oral route from contaminated hands to food items. Controlling the transmission of fecal bacteria, enteric non-lipophilic viruses, and protozoan oocysts, which can contaminate hands with a very high titer, is a particular concern. CDC estimates the non-lipophilic virus, Norovirus (Norwalk-like virus) to be the leading cause of foodborne illness in the United States.

2. EFFICACY AND APPROVAL OF ALCOHOL-BASED HAND GELS

All alcohol-based hand gels applied to human skin are drugs, and must be covered by FDA's Over-the-Counter (OTC) Drug Review or by an FDA-approved new drug application to be legally marketed in the United States. Further, all ingredients, including emollients and perfumes that are constituents of alcohol hand gels used in retail and food service operations must be approved as indirect food additives.

Some in vitro and in vivo published studies suggest that alcohol-based hand gels are highly effective against nosocomial bacterial pathogens of major concern in health-care settings. However the antimicrobial efficacy of alcohol-containing handwashes for use in any setting remains under review by FDA. Some published studies also indicate that moisture on the hands may interfere with alcohol efficacy. In addition, alcohol has been shown to be ineffective against protozoan oocysts and, depending on the alcohol concentration, time, and viral variant, alcohol may not be effective against hepatitis A, or other non-lipophilic viruses.

3. SOIL ON HANDS

The types and levels of soil on the hands of health-care workers differ from food service/retail workers. The type of activities conducted in retail and food service may lead to increased potential for fatty and proteinaceous materials to be on the hands. The fatty and proteinaceous materials may or may not be visible on the hands. Proteinaceous material is known to interfere with and neutralize alcohol efficacy. Fatty substances can coat and protect pathogens from the action of alcohol. Soap, friction, and running water effectively remove the proteinaceous and fatty materials, and reduce pathogens of concern.

Existing data do not demonstrate that alcohol-based hand gel effectively reduces important infectious foodborne pathogens at levels that occur on food workers' hands, especially if the hands are soiled with fatty and proteinaceous materials. Even in health-care settings, the CDC guidelines recommend soap and water handwashing on hands that are visibly soiled, or contaminated with proteinaceous material, rather than using the alcohol-based sanitizers.

CONCLUSION

Proper handwashing, as described in the Food Code continues to serve as a vital and necessary public health practice in retail and food service. **Using alcohol gel in place of handwashing in retail and food service does not adequately reduce important foodborne pathogens on foodworkers' hands. Concern about the practice of using alcohol-based hand gels in place of hand washing with soap and water in a retail or food service setting can be summarized into the following points:**

- * Alcohols have very poor activity against bacterial spores, protozoan oocysts, and certain nonenveloped (nonlipophilic) viruses; and**
- * Ingredients used in alcohol-based hand gels for retail or food service must be approved food additives, and approved under the FDA monograph or as a New Drug Application (NDA); and**
- * Retail food and Food Service work involves high potential for wet hands and hands contaminated with proteinaceous material. Scientific research questions the efficacy of alcohol on moist hands and hands contaminated with proteinaceous material.**

FDA and CDC continue to work together to review new data and assure the best public health measures are in place for retail and food service establishments.

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